NOV - 1 2004

K042916

Unit 15,
Belleknowes Ind.Est.,
Inverkeithing, Fife
KY11 1HZ
Tel. 01383411555
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510(k) SUMMARY

Submitted by Dr John Colles, Innovations Director
Contact Dr John Colles. Telephone as above or Mobile no. 07786518919
Date: 15-04-04

Name of Device.

Proprietary Name:.....SAVEDENT™ BLUE
Classification Name:.....Ultraviolet activator for polymerisation
Common Name:.....Light Curing Unit.

Classification........Ultraviolet activator under 872.3260 (class 2) Dental panel, product code EBZ.

Predicate Device.
Elipar™ Freelight from 3M ESPE.....K011154 (Product Code: EBZ).

Description for the Premarket notification.

SAVEDENT™ BLUE is a LED based curing light intended to polymerise and therefore cure, harden or set resin or glass ionomer based dental materials used for restorative, sealing or cementing procedures. It is a lightweight handheld unit delivering up to 1000mW/cm^2 for set times between 10 and 40 seconds.
It has the same intended purpose, uses the same technology as and offers the same significant output parameters (power density and wavelength) as the predicate device and is therefore substantially equivalent to it.
Comparative tests have demonstrated that SAVEDENT™ BLUE provides the same or better performance in terms of cure depth for a given exposure time as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2004

Denfotex Light Systems Limited
C/O Mr. William J. Sammons
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K042196
Trade/Device Name: SAVEDENT BLUE
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: October 19, 2004
Received: October 19, 2004

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

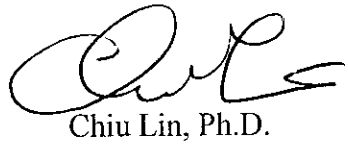
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K042196

Device Name: SAVEDENT BLUE

Indications For Use:

Light source for the activation of light cured resin polymers and glass ionomer materials used in dentistry as pit and fissure sealants, restorative materials, and bonding materials.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042196